REMARKS

Claims 3-6 are pending in this application. Non-elected claims 1-2 and 7-34 were canceled without prejudice to or disclaimer of the underlying subject matter in the Response to Office Action filed on August 19, 2004. By way of the forgoing amendment, claims 3, 4, and 6 have been amended, and claim 5 has been canceled without prejudice to or disclaimer of the underlying subject matter. Support for the amendments can be found throughout the specification, in the sequence listing, and in the claims as originally filed, for example in the specification at page 12 lines 7-10, page 15, lines 10-18, page 17, lines 9-29. Upon entry of these amendments, amended claims 3, 4, and 6 will be pending. No new matter enters by way of these amendments.

1. Status of Prosecution

An appeal brief was filed on October 11, 2005. The Examiner indicates in the Office Action, however, that "[I]n view of the appeal brief filed on 10/11/2005, PROSECUTION IS HEREBY REOPENED." Office Action at page 2. Moreover, the Examiner indicates that "[n]ew grounds of rejection are set forth" in the Office Action. *Id.* The Examiner also requires the Applicant to either: "(1) file a reply under 37 CFR 1.111...; or (2) request reinstatement of the appeal." *Id.* Applicants acknowledge that prosecution has been reopened in the present Office Action and Applicants submit the instant amendment and response under 37 CFR 1.111.

Applicants also acknowledge that the Office has not addressed Applicants' arguments presented in the Appeal Brief filed on October 11, 2005 because "the present written description, enablement and 102 rejections address new issues, not previously before articulated." Office Action at page 3.

2. Objections to the Claims

The Examiner has objected to claim 6 for allegedly "omitting the word 'acid' after the word 'amino'." Office Action at page 3. Applicants note that the listing of the claims in the Appeal Brief filed October 11, 2005 inadvertently omitted the word "acid" in claim 6. Applicants however, have amended claim 6 herein to replace the omitted term.

Applicants acknowledge and thank the Examiner for indicating that "[c]laim 6 is objected to but would be allowable if the claim was rewritten to correct the deficiencies discussed above." Office Action at page 15. Applicants assert that the objections to claim 6 have been overcome by the present amendments and claim 6 is now in condition for allowance.

3. Claim Rejections – 35 U.S.C. § 112, 2nd Paragraph, Indefiniteness

Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Office Action at page 3.

Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert*

denied, 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of claim 4 read in light of the disclosure of the specification.

The Examiner alleges that claim 4 is indefinite because "Applicants do not explicitly define 'stringent conditions' in the claims or in the specification." Office Action at page 3. Applicants respectfully disagree, however, in order to facilitate allowance, claim 4 has been amended to recite that the nucleic acid molecule can hybridize under the conditions of "6.0X sodium chloride/sodium citrate (SSC) at about 45° C followed by a wash of 0.2 X SSC at 50° C for about 20 minutes." Accordingly, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

4. Claim Rejections – 35 U.S.C. § 112, 1st Paragraph, Written Description

Claims 3-5 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at pages 3-7. As claim 5 has been canceled without prejudice to or disclaimer of the underlying subject matter, Applicants respectfully traverse this rejection and provide arguments as the rejection pertains to claims 3 and 4.

The Examiner acknowledges that Applicants have

> isolated a cDNA clone from soybean, SEQ ID NO: 1, that encodes SEQ ID NO; 2, that shares sequence identity with the *Arabidopsis* ANT protein. Applicants further disclose that SEQ ID NO:2 contains two AP2 DNA binding domains that share homology with the *Arabidopsis* ANT polypeptide, four conserved segments were identified in the N-terminal [region] before the AP2 DNA binding domains, suggesting a possible functional role, and the C-terminal

> sequence of SEQ ID NO;2 bears little homology with that of *Arabidopsis* ANT protein but does share conserved segments with another ANT-like clone isolated from soybean. Applicants suggest that these C-terminal segments may perform additional or distinguishable functions from the *Arabidopsis* ANT polypeptide.

Office Action at page 5 (internal parentheticals omitted). However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that the specification fails "to describe a representative number of polynucleotide sequences encoding SEQ ID NO: 2 falling within the scope of the claimed genus of polynucleotides, comprising sequences that encode polypeptides that comprise any two amino acids of SEQ ID NO:2, or encode a polypeptide exhibiting 60% amino acid identity with SEQ ID NO:2, ... , and wherein any of the encoded proteins have the same function/activity as the protein encoded by SEQ ID NO:1." *Id.* at page 6. The Examiner further alleges that "Applicants do not identify essential regions of SEQ ID NO:2 encoded by SEQ ID NO:1...." Office Action at page 5. Apparently, the Examiner contends that "[s]ince the genus of proteins of SEQ ID NO:2 have not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims." *Id.* at page 7. Applicants respectfully traverse.

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of

the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of nucleic acid molecules encoding the sequence of SEQ ID NO: 2, as well as complements and variations thereof. Applicants have therefore satisfied the test for written description.

Applicant's present disclosure not only provides the nucleic acid sequences required by the claims as amended (*e.g.*, those encoding SEQ ID NO: 2), but further describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (*see, e.g.,* specification at page 39, line 30 through page 42, line 20). The specification also describes, for example, nucleic acid molecules comprising single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (*see, e.g.,* specification at page 28, lines 21-24), nucleic acid molecules encoding polypeptides having at least 60% sequence identity with SEQ ID NO: 2 (*see, e.g.,* specification at page 15, lines 19-24), nucleic acid molecules encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 15, line 19 through page 16, line 12), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 37, line 31 through page 38, line 2), plant and other homologue proteins and nucleic acid molecules (*see, e.g.,* specification at page 38, lines 3-13) and the disclosure of high stringency hybridization conditions (*see, e.g.,* specification at page 17, line 9 through page 18, line 7). Despite the numerous variations described for the claimed nucleic acid molecules in

the present specification, the Examiner still maintains that "Applicants fail to describe a representative number of polynucleotide sequences encoding SEQ ID NO: 2 falling within the scope of the claimed genus of polynucleotides." Office Action at page 6. The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Applicants have provided a detailed chemical structure, *e.g.*., nucleic acid sequences encoding the amino acid sequence of SEQ ID NO: 2. Nucleic acid molecules falling within the scope of claims 3-4 are readily identifiable – *e.g.* they comprise nucleic acid molecules having the nucleic acid sequence which can encode an amino acid sequence that is substantially identical to the sequence of SEQ ID NO: 2. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for the claimed invention. Therefore, claims 3-4 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Rejection Under 35 U.S.C. §112, 1st Paragraph: Enablement

Claims 3-4 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate

in scope with these claims." Office Action at page 7. As claim 5 has been canceled without prejudice to or disclaimer of the underlying subject matter, Applicants respectfully traverse this rejection and provide arguments as the rejection pertains to claims 3 and 4.

The Examiner alleges that "the specification, while being enabling for isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence comprising SEQ ID NO:2, does not reasonably provide enablement for a nucleic acid sequence or its complement, which encode a polypeptide having an amino acid sequence that is substantially identical to a sequence of SEQ ID NO:2, [or] an isolated nucleic acid molecule comprising a nucleotide sequence or its complement, which can hybridize under stringent conditions to a nucleic acid sequence which can encode a protein with substantial identity to SEQ ID NO:2." *Id.* Applicants respectfully traverse this rejection.

The Examiner further alleges that "[t]he claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors." *Id.* at page 8. The Examiner concludes that "given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled." *Id.* at page 10. Applicants respectfully disagree.

It is well established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques" (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid

sequences, Applicants submit the Examiner has not met the required burden. Furthermore, Applicants submit that an analysis of the criteria presented by *In re Wands* supports Applicant's position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides, for example, percent sequence identity, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome. *See, e.g.,* specification at page 14, line 26 through page 16, line 12, page 28, line 25 through page 31, line 28, page 47, line 25 through page 54, line 4 (Examples 1-5) and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth and sixth *Wands* criteria focuses on the nature of the invention, the state of the art and the relative skill in the art. The present invention relates to nucleic

acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 13, line 3 through page 16, line 12 (describing polypeptide molecules and homologues), and page 39, line 4 through page 47, line 17 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative substitutions or use the nucleic acid molecules of the present invention in the disclosed uses. The Examiner cites Lazar *et al.* (1988, Mol. Cell. Biol. 8:1247-1252) and Hill *et al.* (1998 Biochem. Biophys. Res. Comm. 244:573-577) to support the proposition that "[m]aking conservative substitutions does not produce predictable results." Office Action at page 11. However, these references seem to suggest that conservative and non-conservative modifications can be made to an amino acid sequence without altering the encoded protein's function, albeit with reduced activity in some instances. Applicant asserts that the specification discloses sufficient guidance, for example through the 37 working examples, to render these results predictable. *See, e.g.*, Specification at page 10, line 21 through page 16, line 12, and page 47, line 25 through page 85, line 22 (Examples 1-37).

The Office also cites Fourgoux-Nicol *et al.* for the proposition that "the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does

not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe." Office Action at page 11. Applicants submit that the specification provides sufficient guidance to render hybridizations of the claimed nucleic acid molecules under high stringency conditions predictable. As set forth above, the specification provides numerous sequences within the claimed genus and provides numerous working examples utilizing such sequences.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the nucleic acid molecules of claims 3-4. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Moreover, because the above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the Examples, and the claims, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables <u>any</u> mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528,

1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Furthermore, the analysis of the *Wands* factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

6. Claim Rejections – 35 U.S.C. § 102(b)

Claims 3-5 remain rejected under 35 U.S.C. § 102(b) as allegedly "anticipated by Elliott et al. (1996, The Plant Cell 8:155-168)." As claim 5 has been cancelled without prejudice to or disclaimer of the underlying subject matter, Applicants will respond as the rejection pertains to amended claims 3 and 4.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). Applicants submit that Elliot does not anticipate the claims of the present invention.

The Examiner alleges that the cited reference teaches "a nucleic acid sequence that encodes the *Arabidopsis* AINTEGUMENTA (ANT) protein that exhibits 38% identity to Applicants' SEQ ID NO: 2." Office Action at page 10. The Examiner goes on to argue that the "sequence of Elliot et al encodes a protein that is substantially identical to any sequence of SEQ ID NO:2, given that the encoded protein comprises at least any two amino acid residues that are found in Applicants' encoded protein."

Although Applicants disagree, to facilitate prosecution, claim 3 has been amended to recite "the sequence of SEQ ID NO: 2." Whatever else Elliott *et al.* teaches, it does not disclose a nucleic acid molecule comprising a nucleotide sequence, or its complement, which can encode an amino acid sequence that is at least 60% identical to the sequence of SEQ ID NO: 2.

The Examiner has not shown that the amino acid sequence described in Elliot is substantially identity to SEQ ID NO: 2 or that comprises SEQ ID NO:2 containing conservative amino acid substitutions. The Examiner alleges that Elliot describes an amino acid sequence that exhibits 38% identity to Applicants' SEQ ID NO: 2. However, the Examiner defines "'substantially identical' and 'substantial identity' to mean that one amino acid or nucleotide sequence has 60% sequence identity when compared to a reference amino acid or nucleotide sequence." Office Action at page 14. The Examiner fails to show that Elliot discloses an amino acid sequence within the meaning of the term as alleged by the Examiner. As discussed above, to facilitate prosecution, claim 3 has been amended to recite the nucleotide sequence, or its complete complement, can encode a polypeptide having an amino acid sequence that is at least 60% identical to the sequence of SEQ ID NO: 2. Whatever else Elliot *et al.* discloses, it does not disclose or suggest an amino acid sequence that is at least 60% identical to SEQ ID NO: 2. *See, e.g.*, specification at page 15, lines 10-18. As such, whatever else Elliot describes, it at least does not describe a protein with substantial identity to SEQ ID NO:2.

Moreover, the Examiner provides no support for the conclusion that the sequence of Elliot *et al.* can hybridize under high stringency conditions to a nucleic acid sequence encoding a protein having the amino acid sequence of SEQ ID NO: 2. The Examiner

again appears to shift the burden of proof to Applicants to provide evidence that the nucleic acid sequence that encodes the *Arabidopsis* ANT protein would not hybridize to a nucleic acid sequence that encodes SEQ ID NO: 2 under the claimed hybridization conditions. As such, whatever else Elliot *et al.* discloses it does not disclose or suggest a nucleic acid molecule which can hybridize under the recited conditions to a second nucleic acid molecule which can encode the amino acid sequence of SEQ ID NO: 2.

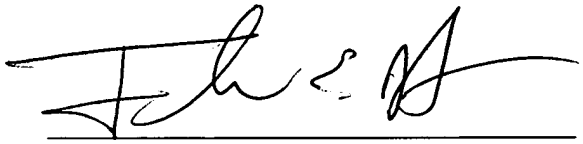
Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate claims 3-4 and the rejection should be withdrawn. Accordingly, for at least the foregoing reasons, the rejection of claims 3-4 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Applicants acknowledge and thank the Examiner for indicating that "claim 6 is deemed free of the prior art." Office Action at page 15.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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